



# Conventional versus computer-assisted surgery in total knee arthroplasty: comparison at ten years follow-up

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## Abstract

**Purpose** Computer-assisted systems (CAS) for total knee arthroplasty (TKA) were expected to result in more accurate prosthesis implantation, better patient outcomes, and longer implant survival when compared to conventional instrumentation (CI). The aim of this study was to compare two groups of patients operated using CAS or CI at ten years follow-up.

**Methods** One hundred twenty TKA patients, 60 using CAS and 60 using CI, were contacted after a decade for follow-up. Eligible patients received radiological examination to assess the lower-limb mechanical axis. They were also clinically assessed using the Knee Injury and Osteoarthritis Outcome Score (KOOS) and the Knee Society Score for Knee (KSS-K) and Function (KSS-F) Scoring. Kaplan-Meier survival analysis was performed to assess revisions, not for post-traumatic reasons.

**Results** In CAS and CI groups, the lower-limb mechanical axis was  $1.7^\circ \pm 2.4^\circ$  and  $1.5^\circ \pm 2.8^\circ$ , respectively; corresponding KOOS values were  $82.3 \pm 14.3$  and  $78.6 \pm 14.4$ ; KSS-K values were  $85.9 \pm 11.1$  and  $85.0 \pm 9.7$ ; KSS-F values were  $82.2 \pm 19.3$  and  $83.8 \pm 18$ . For these assessments, the differences between the two groups were not statistically significant ( $p > 0.05$ ). Two CAS (3.8%) and three CI patients (5.7%) were revised. The Kaplan-Meier analysis showed no significant differences between the two groups.

**Conclusions** No significant differences were found at long-term follow-up in terms of radiographical-clinical outcomes and of implant survival between TKA operated using CAS or CI.

**Keywords** Total knee arthroplasty · Computer-aided surgery · Surgical navigation · Clinical outcome · Long-term follow-up

## Introduction

Total knee arthroplasty (TKA) is an established surgical technique to effectively treat severe knee arthritis [1, 2], in terms of pain relief and functional improvement [3]. Unfortunately, at long-term follow-up, the risk of TKA failure, including revision surgery, still remains a major concern. Improvements in prosthesis modeling, designs, and materials have been made in the last two decades, resulting in better functional improvements and a decrease in TKA failures [2, 4]. Furthermore,

the literature reports that better TKA outcomes, in terms of implant survival, can be derived from accurate prosthesis component positioning [5, 6]. For this purpose, surgical navigation for TKA was developed within computer-assisted surgery (CAS), resulting in encouraging outcomes [7–10] even in the case of large knee deformities [11].

A final mechanical axis, within less than  $3^\circ$  deviation from the neutral position, has been a primary goal in many clinical studies comparing navigated and conventional TKA [6, 12]. Relevant literature showed that TKA performed via CAS resulted in better implant positioning, in terms of neutral mechanical axis restoration, when compared to conventional instrumentation (CI) based techniques [5, 13, 14]. It was expected that CAS would produce better clinical results with respect to traditional manual procedures [14], possibly resulting in smaller long-term revision rates [12]. However, only a few studies have compared CAS versus CI in terms of clinical outcomes and revision rates at mid-term [15, 16] or at long-term follow-up [6, 12].

For these reasons, the present authors initiated this study 12 years ago, assessing patients enrolled for TKA and

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comparing surgical and clinical results derived from CAS or CI techniques. The initial results at two years follow-up have already been reported [17] and have shown a better component alignment using the CAS technique, although both techniques shared similar initial clinical outcomes. The aim of the present study is to report a ten years follow-up on the same group of patients. The primary hypothesis is that clinical differences, in terms of radiographical and clinical outcomes, exist in TKA performed using CAS or CI, proving the possible superiority of one of these two surgical techniques at long-term follow-up. A secondary hypothesis is that this would result in different implant survivorship.

## Materials and methods

### Patients

One hundred twenty TKA cases were inserted in the present prospective, randomized, controlled study initiated in 2003. These were selected among indications for primary TKA, including primary arthritis, secondary to articular or extrarticular fractures and avascular necrosis. Exclusion criteria were infection and severe knee instability. Among these 120 TKA, 60 TKA were performed using CAS and 60 using CI via block randomization (Table 1). Two different prosthesis designs were implanted in equal number: the Scorpio Posterior Stabilized System (Stryker, Mahwah, NJ, USA) and the Optetrak Posterior Stabilized System (Exactech, Gainesville, FL, USA). The selection of the prosthesis to be implanted in each patient was performed also via block randomization (Table 1). Data related to gender, age, weight, height, preoperative mechanical axis, and tibial posterior slope in the CAS and CI groups were not statistically different, as in the previous study [17], but here the groups are differentiated also for the implanted prosthesis designs.

From November 2012 to December 2015, all patients were contacted for a clinical-radiographical evaluation at ten years follow-up. The mean follow-up time for the available patients was 10.3 years (range from 9.8 to 10.5 years). The follow-up appointment was fixed according to patient availability within  $\pm$  six months from the tenth year deadline. The annexed CONSORT diagram [21] (Fig. 1) reports the TKA enrolment procedure, including details on cases lost at follow-up. In this, all cases of revision surgery, patients' death, and generic unavailability to fix a follow-up appointment were recorded (Fig. 1).

Clinical-radiographical outcomes including component alignment data were already reported in a previous publication [17] based on two years follow-up data, together with demographic and preoperative data at the time of TKA. As for the specific aim of the present study, radiographical evaluations, together with additional clinical assessment, were performed for the TKA patients available at ten years follow-up.

All investigations were conducted in conformity with ethical principles, and written informed consent was obtained from all patients.

### Surgical techniques

Patient preoperative assessment involved standing long-leg radiographic acquisition, with standard antero-posterior, lateral, and Merchant views; the posterior slope of the tibial component and the lower-limb mechanical axis, i.e. the angle between the centres of the femoral head, knee, and ankle (Table 1) were measured on radiographs [18].

A single senior surgeon, expert in TKA with both CAS and CI techniques, performed all procedures using an anterior-longitudinal approach with medial-parapatellar arthrotomy.

In CAS group, an image-free knee navigation system (Stryker-Leibinger, Freiburg-im-Breisgau, Germany) was used. In this technique, an initial anatomical survey was performed by digitizing a number of references [9] to define relevant references then used to target accurate orientations

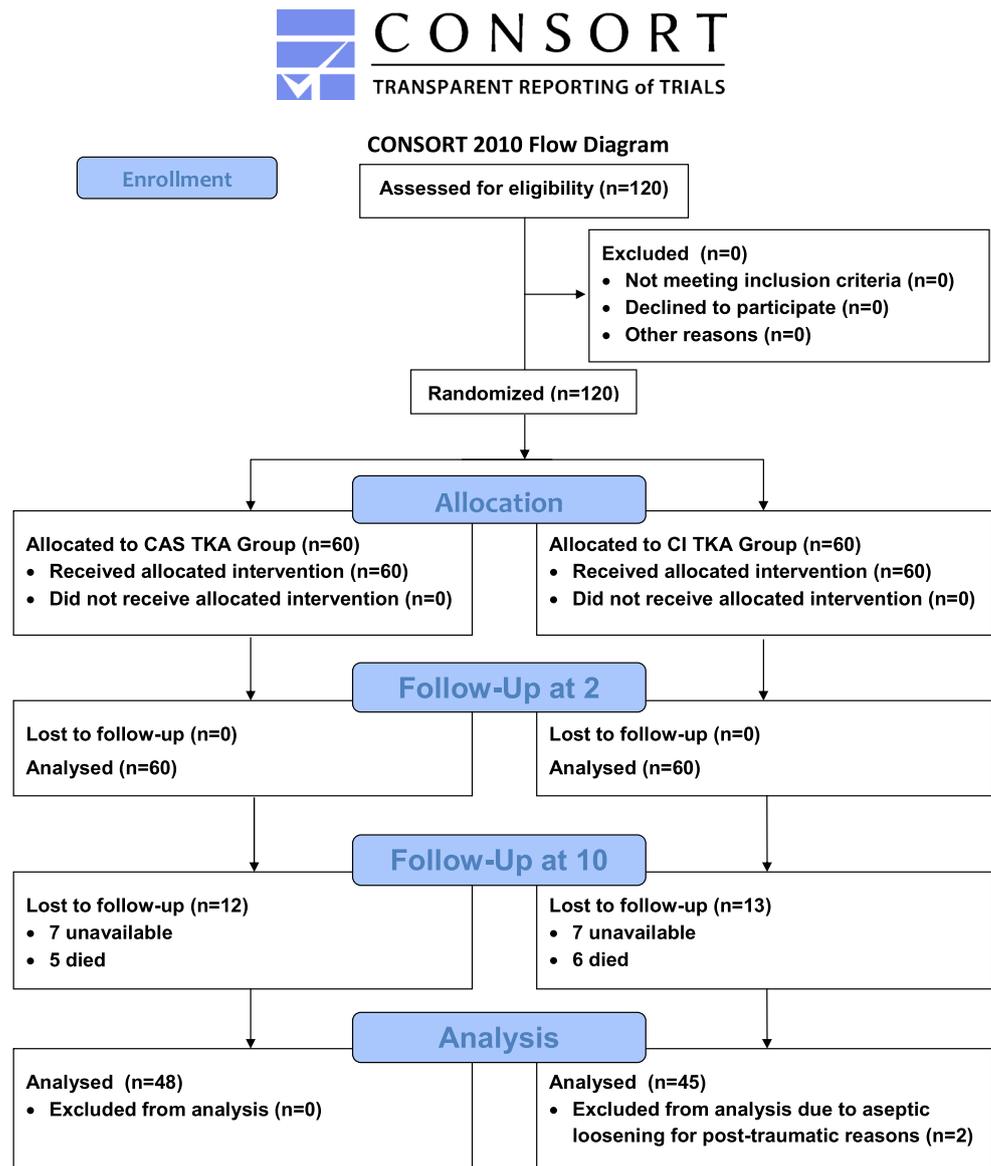
**Table 1** Demographic data and preoperative lower-limb mechanical axis in CAS and CI groups, differentiated also according to the TKA prosthesis designs

Parameter	CAS			CI		
	Scorpio	Optetrak	<i>p</i> value	Scorpio	Optetrak	<i>p</i> value
Number of patients	30	30	NS	30	30	NS
Age (years)	69.5 $\pm$ 6.5*	68.0 $\pm$ 6.1*	NS	69.3 $\pm$ 7.5*	71.8 $\pm$ 7.9*	NS
Gender (male/female)	15/15	15/15	NS	15/15	15/15	NS
Weight (kg)	80.2 $\pm$ 14.3*	80.9 $\pm$ 13.8*	NS	75.4 $\pm$ 13.0*	77.8 $\pm$ 12.2*	NS
Height (cm)	162.6 $\pm$ 7.5*	166.5 $\pm$ 8.3*	NS	161.4 $\pm$ 7.7*	164.1 $\pm$ 8.5*	NS
Mechanical axis	7.0 $\pm$ 8.3* varus	7.4 $\pm$ 8.6* varus	NS	7.2 $\pm$ 6.9* varus	7.7 $\pm$ 7.5* varus	NS

NS not significant

\*Mean  $\pm$  standard deviation

**Fig. 1** CONSORT flow diagram of the randomized controlled trial



for all bone cuts and positioning of prosthesis components [17, 19]. Particularly, on the femur, a distal transverse cut at  $0^\circ$  with respect to the femoral mechanical axis was targeted; the bisector between the Whiteside's line [37] and the perpendicular axis to the surgical transepicondylar axis was targeted for the axial internal-external component alignment. On the tibia, a proximal transverse cut at  $0^\circ$  with respect to the tibial mechanical axis in the frontal plane and with a sagittal posterior slope equal to the original anatomical slope as calculated on preoperative radiographies was targeted [17, 20]; the axial rotation alignment was achieved using the range-of-movement technique, in which the knee was put through a full range of flexion-extension, allowing the tibial trial to

orientate itself in a best mean position with respect to the femoral component [17].

In CI group, cutting jigs annexed to intra/extramedullary rods were utilized in bone preparation and component alignment [17]. Particularly, on the femur, the distal transverse cut was performed by targeting  $0^\circ$  with respect to the frontal neutral mechanical axis using the distal cutting jig set to the anatomical-to-mechanical-axis angle of the femur as measured on preoperative long-leg radiographies; in the sagittal plane, the femoral component was aligned at  $90^\circ$  with respect to the intramedullary rod; the axial internal-external component alignment was performed as in CAS. On the tibia, the proximal transverse cut was set at  $0^\circ$  with respect to the neutral

frontal mechanical axis using an extramedullary rod and with a sagittal posterior slope equal to the original anatomical slope; the axial internal-external alignment was performed as in CAS.

In all cases the patella was resurfaced, and all the prosthesis components were cemented.

### Follow-up evaluations

All patients available at the follow-up received radiographical examinations [18] to assess relevant lower-limb mechanical axis (tested intra- and inter-observer repeatability by three experienced surgeons in three separate sessions each of ten measurements:  $1.3^\circ \pm 1.4^\circ$  and  $2.3^\circ \pm 1.4^\circ$ ). These patients were also clinically assessed using the Knee Society Score (KSS) [21] and the Knee Injury and Osteoarthritis Outcome Score (KOOS) [22]. KSS combines subjective and objective information of the replaced knee and is divided in two subscales: the Knee Score (KSS-K) and the Function Score (KSS-F), each ranging from 0 to 100 points (representing the worst and the best clinical or functional situations, respectively) [21]. The KOOS holds five separate subscales (Pain, Symptoms, ADL Function, Sport and Recreation Function, Quality of Life) scored from 0 (No Problems) to 4 (Extreme Problems) using the Likert scale, whose sum is transformed to a 0–100 scale, with zero representing extreme knee problems and 100 representing no knee problems [22].

All radiographs and clinical scoring were analyzed by a single independent orthopedic surgeon, who was blinded to the surgical technique used.

### Statistical analysis

With the proposed power of 80% and an  $\alpha$  level of 0.05 for radiographical and clinical evaluations, a sample size of at least 60, subdivided in two subgroups compound of 30 for each TKA prostheses design, was needed for CAS and CI groups. This computation assumes that the general mean difference was  $1.5^\circ$  in radiological evaluations and 10 points in clinical scoring, and the relevant common within-group standard deviation was  $2.0^\circ$  and 15 points, respectively.

The mean lower-limb mechanical axis, KSS-K, KSS-F, and KOOS were calculated in each group, and statistical analysis was performed to identify possible differences between groups. The Kolmogorov-Smirnov test was applied preliminarily to check normality in data distribution; consequently, Student's *t* test or Mann-Whitney-Wilcoxon test was utilized for data comparison between the two groups. Furthermore, in each group, the Kaplan-Meier analysis was used to generate survival curves with 95% confidence intervals, whereas the log-rank test was used to compare relevant survival distributions between the two groups. In all comparisons, a *p* value of less than 0.05 was taken to reveal statistically significant

differences; otherwise, non-significance (NS) was indicated. All calculations were blindly performed by means of Matlab® software package (The MathWorks, Inc., Natick, MA, USA).

## Results

### Radiographical and clinical evaluations

At the follow-up, 7 TKA (11.7%) in CAS group and 7 (11.7%) in CI group were not available; five patients (9.4%) in CAS group and six (11.3%) in CI group had died. Therefore, full radiographical and clinical evaluations were performed on 48 and 47 knees eligible in the CAS and CI groups, respectively (Fig. 1). Furthermore, no statistically significant differences ( $p > 0.1$ ) were found between the Scorpio and Optetrak TKAs within both CAS and CI groups, both in radiographical and clinical evaluations. Accordingly, although reported separately in the tables, results from these two prosthesis designs will be discussed collectively within CAS and CI groups.

The mean  $\pm$  standard deviation values (Table 2) for lower-limb mechanical axis were  $1.7 \pm 2.4$  in CAS and  $1.5 \pm 2.8$  in CI. Relevant difference between the two groups was not significant ( $p = 0.7$ ), confirming what was reported in the previous study based on two years follow-up [17].

The mean  $\pm$  standard deviation values for KOOS (Fig. 2) were  $82.3 \pm 14.3$  in CAS and  $78.6 \pm 14.4$  in CI. The corresponding KSS-K values (Fig. 3) were  $85.9 \pm 11.1$  and  $85.0 \pm 9.7$ , respectively; the corresponding KSS-F values (Fig. 4) were  $82.2 \pm 19.3$  and  $83.8 \pm 18.0$ , respectively. For all these assessments, the differences between CAS and CI groups were not statistically significant (KOOS:  $p = 0.12$ ; KSS-K:  $p = 0.42$ ; KSS-F:  $p = 0.74$ ).

### Survivorship analysis

In both CAS and CI groups, no revision cases were detected among the patients who died before the follow-up. In CAS Group, two TKA were revised due to aseptic loosening of the tibial component, representing 4.2% of the eligible 48 knees. In CI group, three TKA were revised for aseptic loosening of the tibial component, this represents 6.4% of the eligible 47 knees. In CI group, two additional revision surgeries were found, due to factors not strictly related to prosthetic component positioning: one was due to insert dislocation subsequent to a fall, and one was a consequence of a periprosthetic fracture. Both were excluded from the statistical analysis because patients were revised for post-traumatic reasons and not for pure implant failure. Based on these considerations, relevant overall Kaplan-Meier analysis performed between these two groups (Fig. 5) resulted in a non-statistically significant difference in terms of implant survivorship ( $p = 0.9$ ).

**Table 2** Post-operative lower-limb mechanical axis and clinical scores in CAS and CI groups differentiated also according to the TKA prosthesis designs

Parameter	CAS			CI		
	Scorpio	Optetrak	<i>p</i> value	Scorpio	Optetrak	<i>p</i> value
Mechanical axis	1.2 ± 2.4	2.0 ± 2.3	NS	1.6 ± 2.9	1.3 ± 2.6	NS
KOOS	82.2 ± 13.5	82.5 ± 15.5	NS	82.2 ± 12.2	75.0 ± 15.8	NS
KSS-K	85.5 ± 9.7	86.4 ± 12.6	NS	85.6 ± 9.9	84.4 ± 9.8	NS
KSS-F	85.0 ± 17.2	79.1 ± 21.4	NS	87.4 ± 16.2	78.3 ± 20.6	NS

NS not significant  
 \*Mean ± standard deviation

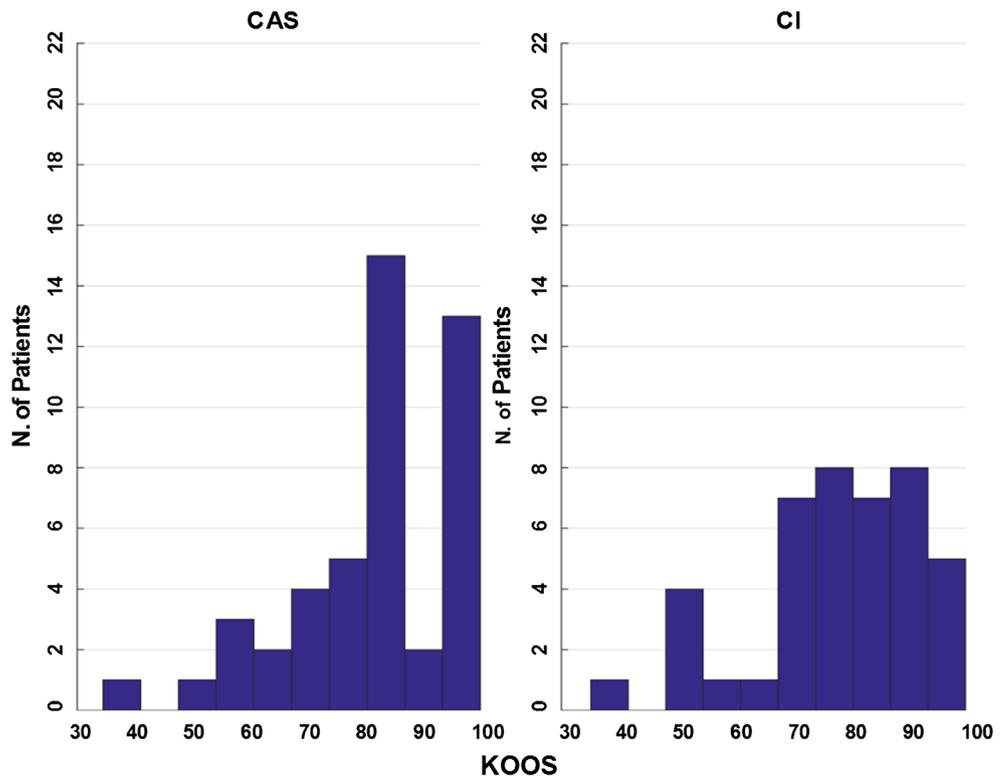
### Discussion

This study reported radiographical and clinical outcomes as well as survival rates at ten years follow-up in two TKA patient cohorts using either CAS or CI technique. As for the two study hypotheses, relevant results show that no statistically significant differences were found between the two groups in terms of lower-limb mechanical axis, clinical scoring, and implant survival rate, thus proving that neither technique is superior to the other in terms of these outcomes.

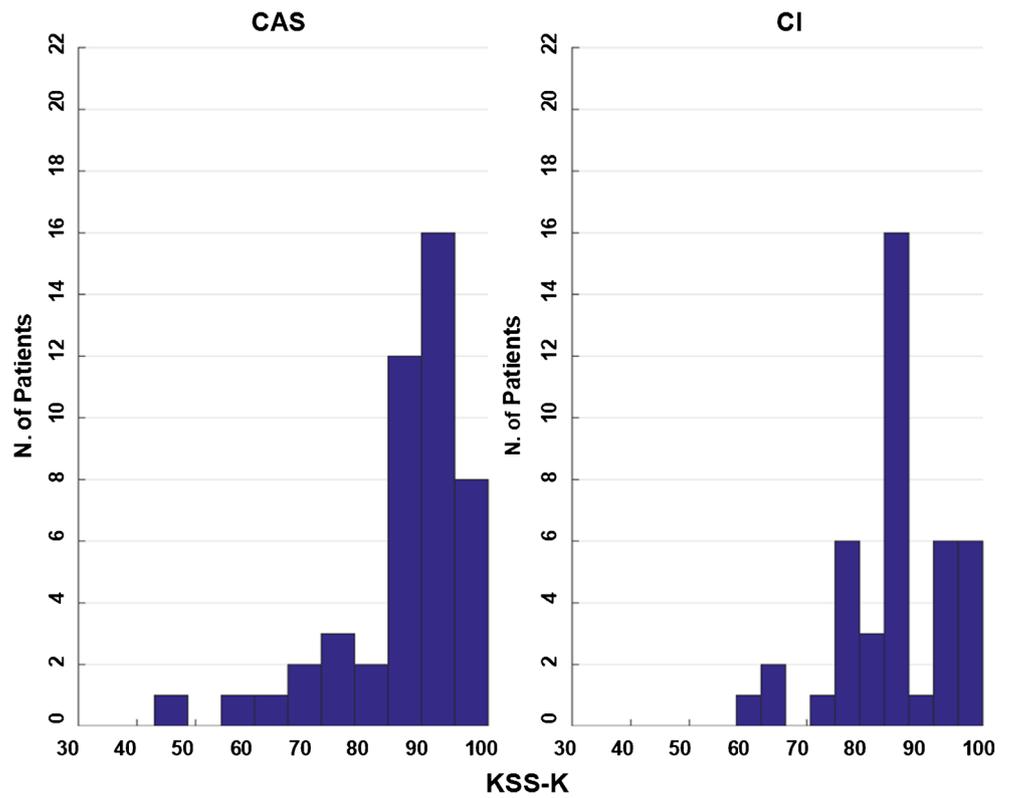
An accurate TKA prosthesis positioning is widely considered an important predictor of patient satisfaction and implant durability [2, 5, 15]. For this reason, CAS was introduced to achieve better prosthesis implantation, and higher accuracy in component alignment was reported for navigated TKA surgical procedures [2], especially for the femoral component [13].

However, in the literature no significant associations between better component alignments, typically using CAS, and better functional outcomes have been reported, particularly at long-term follow-up, and this has resulted recently in a more conscious understanding of CAS technology by the scientific community, despite public enthusiasm [23]. Furthermore, in other studies comparing CAS and CI, no evidence of statistically significant differences, based on the most common clinical evaluations, was reported [24, 25]. Only a few studies have shown better clinical outcomes in patients operated with CAS [5, 6, 15]; however, a major limitation for these studies is the follow-up time, generally mid-/short-term. At long-term follow-up, only a few recent studies compared CAS and CI in a large cohort of TKA patients [6, 12, 26]. Two of these studies [12, 26] observed no differences in clinical function, alignment and survival rates between the two groups, though

**Fig. 2** KOOS scores in CAS and CI TKA patients



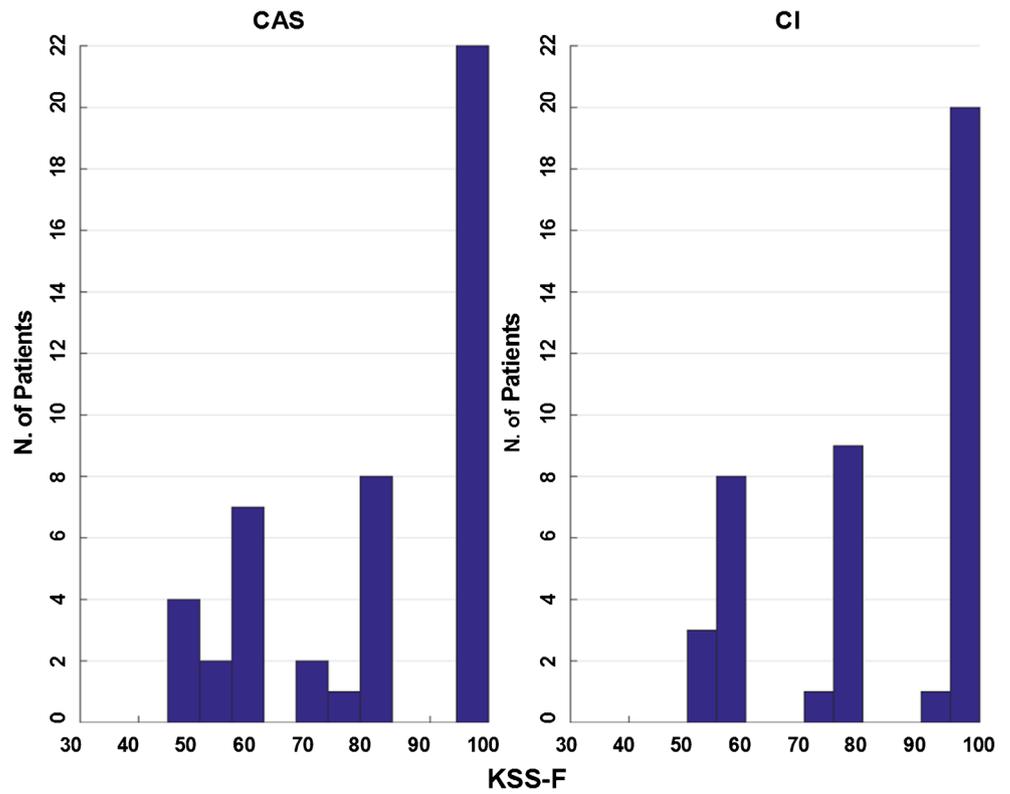
**Fig. 3** KSS-K scores in CAS and CI TKA patients



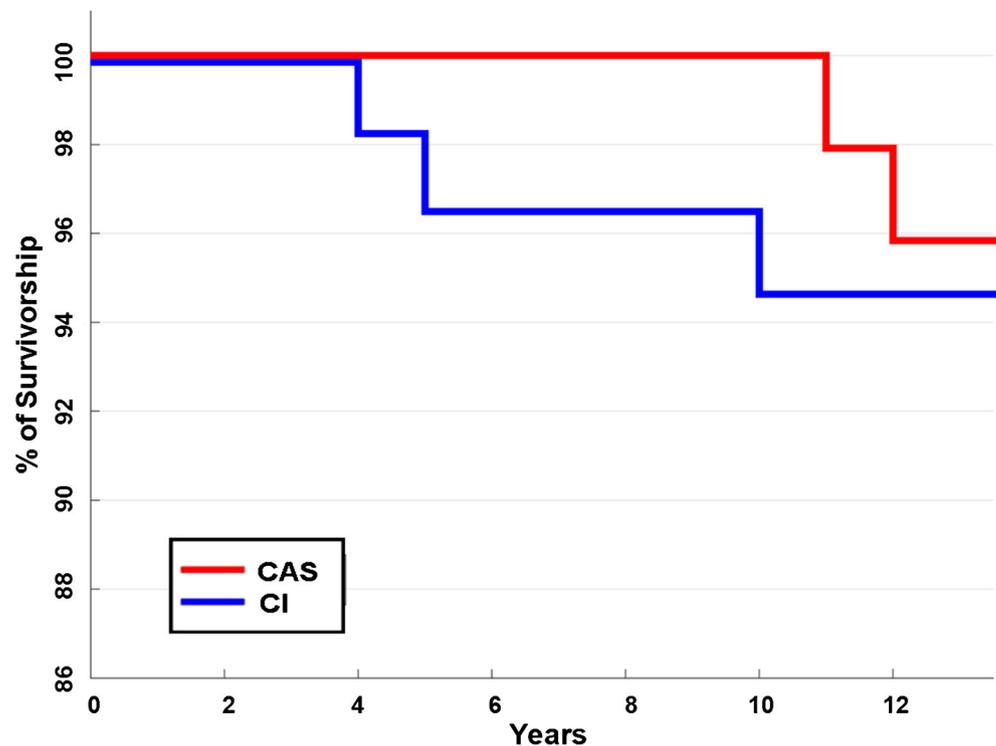
young bilateral patients were analyzed and a high number of patients lost at follow-up were reported. These observations

were consistent with the other study [6], but this concluded that CAS seems to improve TKA survivorship when

**Fig. 4** KSS-F scores in CAS and CI TKA patients



**Fig. 5** Kaplan-Meier survival in CAS and CI TKA patients



compared to CI. All these results however compare well with those reported in the present study, where survival, KOOS, and KSS analyses do not reveal long-term statistically significant differences between these two groups.

These findings do not necessarily diminish the values of CAS. When these systems were introduced into routine TKA more than 15 years ago, the main surgical goal was the achievement of a neutral mechanical axis at the operated limb. Recently, it has been shown that leg alignments within  $\pm 3^\circ$  from the neutral mechanical axis are not strictly associated to longer implant survival [2, 27]. Rather, it has been suggested that slight under-correction of knee deformity results in better clinical outcomes [28]. Moreover, the new concept of kinematic alignment has been later successfully introduced [29], which recommends for patient-specific component alignments according to original knee morphology [30]. Similar debates are still in progress, i.e., the best options for the posterior slope of the tibial component [31]. Regardless of surgeons' preferences, surgical navigation can support successfully the achievements of these alignment goals for each single patient; in addition to standard primary TKA, this has worked also in knee revision surgery and unicompartamental arthroplasty [32, 33]. TKA survivorship is hindered by post-operative patellar maltracking [34], but now CAS procedures can be implemented for best patellar component positioning also in case of resurfacing during surgery [20].

Among the strengths of this study, there is the long-term follow-up, necessary to assess the final effects of TKA, and the large population size analyzed. In the literature, only a few

studies reported larger populations at long-term follow-up [12, 26], though basically comparable to those analyzed here. Similarly to the other studies, here a number of patients were also lost at follow-up, generally because of death or generic unavailability non related to TKA. Though power analysis had been performed, the smaller number of patients might limit the final results, and a risk of type-II error may occur as pointed out in similar studies [12, 26]. Another limitation can be the age of the analyzed patients, complicated by the long-term follow-up. Furthermore, a number of patients reported general difficulties in locomotion activities caused by pain and other disorders at the hip, ankle, or back. Possible comorbidities may have affected the present clinical results, independently from the function of the replaced knee, and therefore independently from adopted TKA surgical technique. In addition, the KOOS questionnaire is more about the single replaced knee, and therefore is not the best tool to identify overall patient condition. However, its adoption here is in combination with KSS, and this should result in more objective and comprehensive patients evaluations.

In conclusion, the results of this study reveal no significant differences in terms of clinical outcomes or implant survival between TKA patients operated using CAS or CI. More specifically, when TKA is performed targeting a neutral mechanical alignment, surgical navigation does not necessarily bring benefits at long-term follow-up compared to conventional techniques. In the future, a possible development of this study could look at the correlation between failure of the implant and deviation of the mechanical axis.

## Compliance with ethical standards

**Conflict of interest** The authors declare that they have no conflict of interest.

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